This brief contains items under the following headings as required by 37 C.F.R. § 41.37:

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The final page of this brief bears the attorney's signature.

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is:

Boston Scientific Scimed, Inc., a corporation established under the laws of the State of Minnesota and having a principal place of business at One Scimed Place, Maple Grove, MN 55311, U.S.A.

II. RELATED APPEALS AND INTERFERANCES

The present case (Application 10/081,641) was previously appealed by the filing of a Notice of Appeal on March 1, 2006, an Appeal Brief on July 31, 2006, and an Amended Appeal Brief on August 28, 2006. Prosecution was reopened by a Non-Final Office Action dated November 16, 2006. The Appeal did not go to the Board of Patent Appeals and Interferences.

Appellant is unaware of any other related appeals, judicial proceedings, or interferences.

III. STATUS OF CLAIMS

A. Total Claims: 1-51

B. Current Status of Claims:

1. Claims canceled: 2, 30, 34-46, and 49
2. Claims withdrawn: 9, 12-16, 18-29, 48, and 50
3. Claims pending: 1, 3-8, 10-11, 17, 31-33, 47, and 51
4. Claims allowed: None
5. Claims rejected: 1, 3-8, 10-11, 17, 31-33, 47 and 51
6. Claims objected to: None
7. Claims on Appeal: 1, 3-8, 10-11, 17, 31-33, 47, and 51

IV. STATUS OF AMENDMENTS

Dependent claims 32, 33, and 51 were amended subsequent to the Final Office Action of December 24, 2009 and subsequent to the filing of the Notice of Appeal on February 23, 2010 by an after-appeal amendment filed on April 9, 2010. Prior to the amendment filed April 9, 2010, dependent claims 32, 33, and 51 depended from canceled claim 30. Appellant amended claims 32, 33, and 51 to depend from independent claim 1. Appellant respectfully submits that such amendment presented rejected dependent claims 32, 33, and 51 in better form for consideration on appeal per 37 C.F.R. § 41.33; 37 C.F.R. § 1.116; and MPEP § 1206.

Appellant believes that the after-appeal claim amendments filed April 9, 2010 will be entered prior to consideration of the present Appeal by the Board. Accordingly, Appellant has presented dependent claims 32, 33, and 51 herein as depending from independent claim 1.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Independent Claim 1

Independent claim 1 recites an introducer (Fig. 2: 100), having a retrograde portion (Fig. 2: 102) and an anterograde portion (Fig. 2: 104), for deployment of an endoluminal device (Fig. 2: 130) in a body lumen in a distal location from a proximal location (pg. 3, ln. 18-20; pg. 7, ln. 20-22; pg. 14, ln. 3-16), the device (Fig. 2: 130) having a compressed configuration and an expanded configuration (pg. 1, ln. 18 – pg. 2, ln.10), the introducer (Fig. 2: 100) comprising:

a shaft (Fig. 2: 106) having a distal tip (Fig. 2: 124) (pg. 2, ln. 23-26; pg. 3, ln. 20-21; pg. 4, ln. 25-29; pg. 7, ln. 22-24; pg. 8, ln. 13-19; pg. 8, ln. 31 – pg. 9, ln. 2; pg. 9, ln. 19-23);

an inner sheath (Fig. 2: 108) mounted concentrically over the shaft (Fig. 2: 106), wherein the endoluminal device (Fig. 2: 130) is mounted concentrically over the inner sheath (Fig. 2: 108) in the compressed configuration (pg. 3, ln. 20-22; pg. 4, ln. 29 – pg. 5, ln. 3; pg. 7, ln. 22-24);

an anterograde sheath (Fig. 2: 126) attached proximally to the distal tip (Fig. 2: 124), mounted over at least a distal portion of the endoluminal device (Fig. 2: 130) in the anterograde portion (Fig. 2: 104) of the introducer (Fig. 2: 100) (pg. 3, ln. 22-24; pg. 4, ln. 25-26; pg. 8, ln. 15-18), the anterograde sheath (Fig. 2: 126) having an open proximal end such that distal movement of the anterograde sheath (Fig. 2: 126) unsheathes the portion (Fig. 2: 135) of the endoluminal device (Fig. 2: 130) contained thereunder (pg. 4, ln. 26-29; pg. 5, ln. 8-12 and 20-21; pg. 9, ln. 19-20; pg. 10, ln. 3-9; Fig. 2 and Fig. 3: 250);

anchoring means (Fig. 2: 120) in at least one of the retrograde portion (Fig. 2: 102) or the anterograde portion (Fig. 2: 104) (pg. 3, ln. 25-29; pg. 5, ln. 20) configured to:

engage and anchor only a proximal portion (Fig. 2: 133) of the endoluminal device (Fig. 2: 130) after unsheathing of a distal portion (Fig. 2: 135) of the endoluminal device (Fig. 2: 130) (pg. 3, ln. 25-27; pg. 4, ln. 22-25; pg. 5, ln. 7-28; pg. 8, ln. 6-12; pg. 9, ln. 8-14; pg. 10, ln. 1-3 and 7-15; Fig. 3: 240); and

minimize relative axial movement between the engaged and anchored proximal portion (Fig. 2: 133) of the device (Fig. 2: 130) and the body lumen during unsheathing of the distal portion (Fig. 2: 135) of the endoluminal device (Fig. 2: 130) (pg. 10, ln. 1-15); and

a proximally retractable retrograde sheath (Fig. 2: 112 and Fig. 3: 230) mounted concentrically over the shaft (Fig. 2: 106) and inner sheath (Fig. 2: 108) in the retrograde portion (Fig. 2: 102) of the introducer (Fig. 2: 100) and extending distally over a retrograde portion (Fig. 2: 133) of the endoluminal device (Fig. 2: 130) (pg. 3, ln. 29-31; pg. 5, ln. 3-6), wherein the retrograde sheath (Fig. 2: 112) and the anterograde sheath (Fig. 2: 126) are laterally spaced (Fig. 2: 132) from one another at least when the retrograde sheath (Fig. 2: 112) is proximally retracted (pg. 8, ln. 20-21).

1. Claim 3 depends from independent claim 1 and recites that the anchoring means (Fig. 2: 120) comprises an inflatable balloon (Fig. 2: 120) at or near a proximal end (Fig. 2: 131) of the device (Fig. 2: 130) (pg. 3, ln. 28-31; pg. 4, ln. 22-25; pg. 5, ln. 20-28; pg. 8, ln. 6-12; pg. 9, ln. 8-12 and 23-26; pg. 10, ln. 1-3).

2. Claim 4 depends from dependent claim 3 and recites that the inner sheath (Fig. 2: 108) defines a lumen connected to an inner region of the inflatable balloon (Fig. 2: 120) for communication of a fluid to the balloon (Fig. 2: 120) for inflation of the balloon (Fig. 2: 120) (pg. 4, ln. 31 – pg. 5, ln. 6; pg. 8, ln. 6-9; pg. 9, ln. 12-19).

3. Claim 5 depends from dependent claim 3 and recites that the inflatable balloon (Fig. 2: 120) is mounted concentrically underneath a retrograde portion (Fig. 2: 133) of the endoluminal device (Fig. 2: 130) (pg. 4, ln. 22-25; pg. 6, ln. 4-7).

4. Claim 6 depends from dependent claim 5 and recites that the proximally retractable retrograde sheath (Fig. 2: 112 and Fig. 3: 230) extends

distally over the balloon (Fig. 2: 120) (pg. 3, ln. 29-31; pg. 5, ln. 3-6).

5. Claim 7 depends from dependent claim 6 and recites that the introducer (Fig. 2: 100) further comprises a medial sheath (Fig. 2: 110) mounted concentrically between the inner sheath (Fig. 2: 108) and the retrograde sheath (Fig. 2: 112) in the retrograde portion (Fig. 2: 102) of the introducer (Fig. 2: 100) (pg. 3, ln. 31 – pg. 4, ln. 2; pg. 7, ln. 22-28).

6. Claim 8 depends from dependent claim 7 and recites that the medial sheath (Fig. 2: 110) has a distal end (Fig. 2: 111) that terminates proximal of the balloon (Fig. 2: 120) (pg. 3, ln. 31 – pg. 4, ln. 2; pg. 7, ln. 26-28).

7. Claim 10 depends from independent claim 1 and recites that the introducer (Fig. 2: 100) further comprises a radial spacer (Fig. 2: 125) for providing sufficient space between the inner sheath (Fig. 108) and the anterograde sheath (Fig. 2: 126) to contain the endoluminal device (Fig. 2: 130) (pg. 8, ln. 13-19).

8. Claim 11 depends from dependent claim 10 and recites that the radial spacer (Fig. 2: 125) is attached proximally to the distal tip (Fig. 2: 124) (pg. 8, ln. 14-15).

9. Claim 17 depends from independent claim 1 and recites that the introducer (Fig. 2: 100) further comprises:

a medial sheath (Fig. 2: 110) mounted concentrically between the inner sheath (Fig. 108) and the retrograde sheath (Fig. 2: 112) in the retrograde portion (Fig. 2: 102) of the introducer (Fig. 2: 100) and terminating (Fig. 2: 111) proximally of a proximal end (Fig. 2: 131) of the endoluminal device (Fig. 2: 130) (pg. 3, ln. 31 – pg. 4, ln. 2; pg. 7, ln. 22-28).

10. Claim 31 depends from claim 1 and recites that the

anterograde portion (Fig. 2: 104) extends over a greater length of the endoluminal device (Fig. 2: 130) than the retrograde portion (Fig. 2: 102) (pg. 14, ln. 3-16).

11. Claim 32 depends from independent claim 1 and recites that the retrograde sheath (Fig. 2: 112) and the anterograde sheath (Fig. 2: 126) are laterally spaced (Fig. 2: 132) from one another before the retrograde sheath (Fig. 2: 112) is proximally retracted (pg. 8, ln. 20-22).

12. Claim 33 depends from independent claim 1 and recites that the retrograde sheath (Fig. 2: 112) and the anterograde sheath (Fig. 2: 126) laterally overlap (Fig. 2: 140) one another before the retrograde sheath (Fig. 2: 112) is proximally retracted (pg. 8, ln. 20-25).

13. Claim 51 depends from independent claim 1 and recites that the retrograde sheath (Fig. 2: 112) and the anterograde sheath (Fig. 2: 126) abut one another before the retrograde sheath (Fig. 2: 112) is proximally retracted (pg. 8, ln. 20-22).

B. Independent claim 47

Independent claim 47 recites an introducer (Fig. 2: 100) for deployment of an endoluminal device (Fig. 2: 130) in a body lumen in a distal location from a proximal location, the device (Fig. 2: 130) having a compressed configuration and an expanded configuration (pg. 1, ln. 18 – pg. 2, ln..10; pg. 3, ln. 18-20; pg. 7, ln. 20-22; pg. 14, ln. 3-16), the introducer (Fig. 2: 100) comprising:

an anterograde portion (Fig. 2: 104) comprising a distal tip (Fig. 2: 124) and an anterograde sheath (Fig. 2: 126) attached proximally to the distal tip (Fig. 2: 124) and mounted over at least a distal portion (Fig. 2: 135) of the endoluminal device (Fig. 2: 130) in the anterograde portion (Fig. 2: 104) of the introducer (Fig. 2: 100) (pg. 3, ln. 22-24; pg. 4, ln. 25-26; pg. 8, ln. 15-18), the anterograde sheath (Fig. 2: 126) having an open proximal end such that distal movement of the anterograde sheath (Fig. 2: 126) unsheathes the portion (Fig. 2: 135) of the endoluminal device

(Fig. 2: 130) contained thereunder (pg. 4, ln. 26-29; pg. 5, ln. 8-12 and 20-21; pg. 9, ln. 19-20; pg. 10, ln. 3-9; Fig. 2 and Fig. 3: 250);

a shaft (Fig. 2: 106) attached to the distal tip (Fig. 2: 124) and extending concentrically through a central lumen defined by the anterograde portion (Fig. 2: 104) and retrograde portion (Fig. 2: 102) (pg. 2, ln. 23-26; pg. 3, ln. 20-21; pg. 4, ln. 25-29; pg. 7, ln. 22-24; pg. 8, ln. 13-19; pg. 8, ln. 31 – pg. 9, ln. 2; pg. 9, ln. 19-23);

an inner sheath (Fig. 2: 108) mounted concentrically over the shaft (Fig. 2: 106) (pg. 3, ln. 20-22; pg. 4, ln. 29 – pg. 5, ln. 3; pg. 7, ln. 22-24);

a retrograde portion (Fig. 2: 102) including a proximally retractable retrograde sheath (Fig. 2: 112) mounted concentrically over the shaft (Fig. 2: 106) and inner sheath (Fig. 2: 108) in the retrograde portion (Fig. 2: 102) of the introducer (Fig. 2: 100) and extending distally over a retrograde portion (Fig. 2: 133) of the endoluminal device (Fig. 2: 130) (pg. 3, ln. 29-31; pg. 5, ln. 3-6), wherein the retrograde sheath (Fig 2: 112) and the anterograde sheath (Fig. 2: 126) are laterally spaced (Fig. 2: 132) from one another at least when the retrograde sheath (Fig. 2: 112) is proximally retracted (pg. 8, ln. 20-21);

an endoluminal device (Fig. 2: 130) mounted concentrically over the inner sheath (Fig. 2: 108) in the central lumen and having a distal portion (Fig. 2: 135) contained by the anterograde portion (Fig. 2: 104) and a proximal end (Fig. 2: 131) contained by the retrograde portion (Fig. 2: 102) (pg. 3, ln. 20-22; pg. 4, ln. 29 – pg. 5, ln. 6; pg. 8, ln. 9-12), the distal portion (Fig. 2: 135) constrained in the compressed configuration by the anterograde sheath (Fig. 2: 126) and adapted to expand into an expanded state as the anterograde sheath (Fig. 2: 126) is advanced distally (pg. 2, ln. 7-10; pg. 5, ln. 7-19; pg. 6, ln. 4-10; Fig. 3: 250); and

an inflatable balloon (Fig. 2: 120) mounted radially inside only the retrograde portion (Fig. 2: 102) (pg. 3, ln. 28-31; pg. 4, ln. 22-25; pg. 5, ln. 20-28; pg. 8, ln. 6-12; pg. 10, ln. 1-3) and sized to:

engage and anchor the endoluminal device (Fig. 2: 130) proximal end (Fig. 2: 131) against the body lumen after expansion of the proximal end (Fig. 2: 131) into the expanded configuration to minimize relative axial movement between the engaged, anchored, expanded proximal end (Fig. 2: 131) of the device

(Fig. 2: 130) and the body lumen during unsheathing of the endoluminal device (Fig. 2: 130) distal portion (Fig. 2: 135) (pg. 3, ln. 25-27; pg. 4, ln. 22-25; pg. 5, ln. 7-28; pg. 8, ln. 6-12; pg. 9, ln. 8-14; pg. 10, ln. 1-15; Fig. 3: 240); and

engage and anchor only a proximal portion (Fig. 2: 133) of the endoluminal device (Fig. 2: 130) after unsheathing of the distal portion (Fig. 2: 135) of the endoluminal device (Fig. 2: 130) (pg. 3, ln. 28-29; pg. 5, ln. 16-28; pg. 10, ln. 1-6; Fig. 3).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 3-8 were improperly rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement.

B. Whether claims 3-8 were improperly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.

C. Whether claims 1, 10, and 11 were improperly rejected under 35 U.S.C. § 102 as being anticipated by Euteneuer, et al. (U.S. Pat. No. 5,989,280).

D. Whether claims 31-33, 47, and 51 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over Euteneuer, et al. (U.S. Pat. No. 5,989,280).

E. Whether claim 17 was improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over Euteneuer, et al. (U.S. Pat. No. 5,989,280) in view of Zadno-Azizi, et al. (U.S. Pat. No. 6,022,336).

VII. ARGUMENT

A. Appellant's specification describes and fully supports the subject matter of independent claim 1 and dependent claims 3-8.

Appellant respectfully submits that Appellant's specification describes the subject matter of independent claim 1 and dependent claims 3-8 in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the Application was filed, had possession of the claimed invention.

Independent claim 1 recites in part:

> anchoring means in at least one of the retrograde portion or the anterograde portion configured to:
>
> engage and anchor only a proximal portion of the endoluminal device after unsheathing of a distal portion of the endoluminal deice.

Claims 3-8 depend, directly or indirectly, from independent claim 1. Claims 4-8 depend directly or indirectly from dependent claim 3. Dependent claim 3 recites that "the anchoring means comprises an inflatable balloon at or near a proximal end of the device." Claims 3-8 were rejected under § 112, first paragraph, according to the Final Office Action dated December 24, 2009. Specifically, page 2 of the Final Office Action states:

> Therefore, since only the distal end is unsheathed, the proximal end must still be constrained by the retrograde. It then follows that the stent is anchored within the sheath. However, the instant specification teaches the balloon as compressing the expanded stent against a lumen wall and not constraining it within a sheath.

First, Appellant notes that the language of claim one does not specify that "only the distal end is unsheathed." Claim 1 does require that the anchoring means engage and anchor only a proximal portion of the endoluminal device after unsheathing of a distal portion of the endoluminal device. Thus, claim 1 specifies certain characteristics of the introducer after the distal portion is unsheathed.

Appellant's claim 1 also recites that the anchoring means is configured to:

> minimize relative axial movement between the engaged and anchored proximal portion of the device and the body lumen during unsheathing of the distal portion of the endoluminal device.

Thus, Appellant's claim 1 requires that the anchoring means be configured to engage and anchor the device against the body lumen (e.g., after the retrograde portion of the device is unsheathed by proximal retraction of the retrograde sheath).

Second, contrary to the assertion made in the Final Office Action, Appellant's specification teaches that the anchoring means can compress the device against a body lumen and/or against the retrograde sheath. Specifically, page 5, lines 20-28 of Appellant's specification recite:

> Where the anchoring means comprises an inflatable balloon, the method comprises inflating the balloon prior to deployment of the anterograde portion of the endoluminal device and deflating the balloon after deployment of the anterograde portion. Where a retrograde sheath is present, the retrograde sheath may be retracted prior to inflating the balloon, such that the balloon is inflated to anchor the proximal end of the endoluminal device against the body lumen. In the alternative, the balloon may be inflated to anchor the proximal end of the endoluminal device against the retrograde sheath, in which case the retrograde sheath is not retracted until after deflating the balloon after the anterograde portion of the endoluminal device has been deployed

Appellant's Figure 2 further supports this teaching (showing the anchoring means 120 between the inner sheath 108 and the device 130, such that if inflated prior to retraction of the retrograde sheath 112, the retrograde portion 133 of the device 130 would be anchored against the retrograde sheath 112.

Therefore, because Appellant's claim 1 does not state that only the distal end is unsheathed, and because Appellant's specification supports the anchoring means compressing the device against the body lumen and/or against the retrograde sheath, Appellant's claims 1 and 3-8 are fully supported by Appellant's specification. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 112, first paragraph rejection of dependent claims 3-8.

B. Independent claim 1 and dependent claims 3-8 are definite because they particularly point out and distinctly claim the subject matter

recited therein.

Appellant respectfully submits that Appellant's independent claim 1 and dependent claims 3-8 are definite. Relevant portions of claims 1 and 3 are quoted above in Appellant's Argument section A.

First, with respect to claim 1, page 3 of the Final Office Action states, "since only the distal end is unsheathed, the proximal end must still be constrained by the retrograde." As discussed above in Argument section A, the language of Appellant's claim one does not specify that "only the distal end is unsheathed." Furthermore, if the proximal end of the device was still constrained by the retrograde sheath, and the anchoring means was activated (e.g., the balloon inflated), Appellant notes that the device would be anchored against the retrograde sheath as described above in Argument section A.

Second, page 3 of the Final Office Action goes on to state:

> Therefore, since only the distal end is unsheathed, the proximal end must still be constrained by the retrograde. It then follows that the stent is anchored within the sheath. It is then unclear as to how a balloon can anchor and constrain a stent within an outer sheath.

As argued above in Argument section A (see also the quote from Appellant's specification page 5, lines 20-28), if the retrograde sheath has been proximally retracted, the anchoring means (e.g., balloon) can anchor the device against he body lumen wall. If the retrograde sheath has not been proximally retracted, then the anchoring means can anchor the device against the retrograde sheath.

Therefore, because Appellant's claim 1 does not state that only the distal end is unsheathed, and because Appellant's specification supports the anchoring means compressing the device against the body lumen and/or against the retrograde sheath, Appellant's claims 1 and 3-8 are definite because they particularly point out and distinctly claim the subject matter recited therein. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 112, second paragraph rejection of dependent claims 3-8.

C. The Euteneuer reference does not describe each and every element of Appellant's claims 1, 10, and 11.

Appellant respectfully submits that the Euteneuer reference does not describe each and every element of Appellant's independent claim 1. At the outset, Appellant notes that the preamble to claim 1 recites in part, "deployment of an endoluminal device in a body lumen in a distal location from a proximal location." Accordingly, the direction "proximal" means a direction from which the introducer was introduced (e.g., toward its back). And the direction "distal" means in the direction toward which the introducer is introduced (e.g., toward its tip or front). This is further supported by Appellant's specification, which states:

> The term "proximal" as used herein refers to portions of the stent or delivery system relatively closer to this access location, whereas the term "distal" is used to refer to portions farther from the access location.

(Pg. 1, ln. 23 – pg. 2, ln. 2).

1. Euteneuer does not describe "a shaft having a distal tip" as recited in Appellant's independent claim 1.

Page 3 of the Final Office Action cites element 50 of Euteneuer as a "shaft" as recited in Appellant's independent claim 1. Euteneuer identifies element 50 as a guide wire (Col. 6, ln. 49).

Appellant respectfully submits that the guide wire 50 described by Euteneuer cannot be interpreted as a shaft having a distal tip as claimed by Appellant. Appellant's specification specifically distinguishes between Appellant's claimed shaft and a guidewire by stating:

> In step 250, shaft 106 is extended distally to deploy the anterograde portion 135 of device 130. Prior to extending the shaft, the guidewire and retrograde sheath 112 may typically be locked together to prevent movement of the retrograde sheath or the guidewire during extension of the shaft.

(Pg. 9, ln. 19-23). The background of Appellant's specification further distinguishes between internal shafts and guidewires by stating:

> Internal shaft 23 may guide the delivery system through the body lumen over a guidewire (not shown) to the area to be repaired, or may be adapted for inflating a balloon (if applicable), andlor for flushing the system.

(Col. 2, ln. 23-26).

As such, the guide wire 50 described by Euteneuer cannot be interpreted as a shaft having a distal tip as recited in Appellant's claim 1. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 102(b) rejection of independent claim 1 and claims 10 and 11 that depend therefrom.

2. Euteneuer does not describe "an anterograde sheath attached proximally to the distal tip, mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder" as recited in Appellant's independent claim 1.

Pages 3-4 of the Final Office Action cite sleeve 14 of Euteneuer as an "anterograde sheath attached proximally to the distal tip" (of the shaft) as recited in Appellant's independent claim 1. Specifically, pages 3-4 of the Final Office Action state:

> Sleeve (14) is mounted over a distal portion of the stent so that distal movement of the sleeve unsheathes the distal portion of the stent (column 6, line 66 through column 7, line 10). Therefore sleeve (14) clearly overlaps the claimed anterograde sheath. Furthermore, this anterograde sheath of Euteneuer is indirectly attached to the proximal tip of the shaft (50).

Euteneuer describes sleeve 14 as a slipping sleeve used (with slipping sleeve 16) to form a waterproof chamber around a stent 17 carried by the catheter 12. (Col. 5, ln. 56-58). Specifically, Euteneuer states:

> In this embodiment, slipping sleeves 14 and 16 are molded with an approximately 90° knee, shown at 24, and an approximately 45° angle at 26. It has been found experimentally that the 90° knee at 24 and the 45° angle at 26 more easily allow the sleeve membrane material to roll over onto itself. Slipping sleeves 14 and 16 are slid over the catheter and bonded to the catheter at 28, as is well known in the art. The slipping seal 30 is formed a tolerance fit between the

> inner diameter of the seal 30 and the outer diameter of the catheter shaft.

(Col. 6, ln. 21-30).

From a review of Figures 1 and 2 in Euteneuer, slipping sleeve 14 appears to be bonded to the catheter 12 proximal to the stent 17. As such, slipping sleeve 14 is not "attached proximally to the distal tip" (of the shaft) even if the guide wire 50 is interpreted as a shaft having a distal tip. Furthermore, slipping sleeve 16 appears to be bonded to catheter 12 distal to the stent 17, but proximal to the distal end of the guide wire 50. Thus, slipping sleeve 16 is not "attached proximally to the distal tip" (of the shaft) even if the guide wire 50 is interpreted as a shaft having a distal tip. From a review of Figures 1 and 2 of Euteneuer, it is clear that nothing is attached to the distal tip of the guide wire 50. To conclude that the slipping sleeve 14 of the Euteneuer device is "indirectly attached to the proximal tip" and therefore anticipates Appellant's claim would render Appellant's claim limitation meaningless because the only logic that would allow such a conclusion is that any portion of the Euteneuer device can be said to be attached to any other portion of the Euteneuer device, even if nothing is attached thereto.

From a review of Figure 2 of Euteneuer, it is clear that slipping sleeve 14 is not "mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer," as required by Appellant's independent claim 1. Slipping sleeve 14 is located proximal to and over stent 17. Furthermore, distal movement of the slipping sleeve 14 causes the sleeve 14 to cover more of the stent 17, not less. Euteneuer states:

> Slipping sleeves 14 and 16 are formed of a doubled-over section of membrane caused by urging seals 30 of sleeves 14 and 16 axially toward each other. This causes the membranes to roll over from their position as seen in FIG. 1 onto themselves at knees 24 as seen in FIG. 2.

(Col. 7, ln. 1-6).

Finally, the slipping sleeve 14 described by Euteneuer does not have "an open proximal end" as required by Appellant's independent claim 1. The proximal end of the slipping sleeve 14 slides over the catheter with a slipping seal 30 formed

to "a tolerance fit between the inner diameter of the seal 30 and the outer diameter of the catheter shaft." (Col. 6, ln. 26-30). Separating the seal 30 can allow fluid to leak between the inner diameter of the seal 30 and the outer diameter of the catheter shaft. (Col. 6, ln. 35-36).

As such, Euteneuer does not describe "an anterograde sheath attached proximally to the distal tip, mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder". Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 102(b) rejection of independent claim 1 and claims 10 and 11 that depend therefrom.

3. Euteneuer does not describe "a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath in the retrograde portion of the introducer and extending distally over a retrograde portion of the endoluminal device, wherein the retrograde sheath and the anterograde sheath are laterally spaced from one another at least when the retrograde sheath is proximally retracted" as recited in Appellant's independent claim 1.

Page 4 of the Final Office Action cites sleeve 16 of Euteneuer as describing a retrograde sheath "since it is mounted over a proximal portion of the stent such that proximal movement of the sleeve unsheathes the proximal portion of the stent."

In contrast, Euteneuer, in Figures 2 and 3 illustrates that slipping sleeve 16 can slide distally to uncover the stent 17. Slipping sleeve 16 is not mounted concentrically over the guide wire and catheter in the retrograde portion because slipping sleeve is located over and distal of the stent 17. Furthermore, the slipping sleeve 16 is not proximally retractable, because in order to uncover the stent 17, slipping sleeve 16 has to retract distally. Also, the slipping sleeve 16 does not extend distally over the stent 17 because when rolled over to form a chamber with slipping sleeve 14, slipping sleeve 16 slides proximally.

As such, Euteneuer does not describe "a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath in the retrograde portion of the introducer and extending distally over a retrograde portion of the

endoluminal device, wherein the retrograde sheath and the anterograde sheath are laterally spaced from one another at least when the retrograde sheath is proximally retracted". Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 102(b) rejection of independent claim 1 and claims 10 and 11 that depend therefrom.

4. Euteneuer does not describe "anchoring means in at least one of the retrograde portion or the anterograde portion configured to: engage and anchor only a proximal portion of the endoluminal device after unsheathing of a distal portion of the endoluminal device; and minimize relative axial movement between the engaged and anchored proximal portion of the device and the body lumen during unsheathing of the distal portion of the endoluminal device" as recited in Appellant's independent claim 1.

Page 4 of the Final Office Action cites band 18 or 60 of Euteneuer as the anchoring means. Specifically, page 4 states, "The bands also minimize axial movement of the stent since it holds the stent in place against the inner sheath."

In contrast, Appellants claim 1 recites that the anchoring means is configured to "minimize relative axial movement between the engaged and anchored proximal portion of the device and the body lumen during unsheathing of the distal portion of the endoluminal device."

Euteneuer states:

> It can be understood that the thickness of band 60 can be varied as desired to allow for a controlled release of stent 17 in any manner desired by the physician, such as releasing the stent starting from either the proximal or distal end or in other sequential deployments.

(Col. 7, ln. 42-47).

However, in order for the stent 17 to be anchored, a band would have to remain in place. When a band is in place (not dissolved) it anchors the stent 17 not against the body lumen wall, but rather against the catheter. Therefore, any "engaged and anchored" portion of the stent would be "engaged and anchored" against the catheter, not the body lumen.

As such, Euteneuer does not describe anchoring means configured to "minimize relative axial movement between the engaged and anchored proximal portion of the device and the body lumen during unsheathing of the distal portion of the endoluminal device." Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 102(b) rejection of independent claim 1 and claims 10 and 11 that depend therefrom.

5. Euteneuer does not describe "a radial spacer for providing sufficient space between the inner sheath and the anterograde sheath to contain the endoluminal device" as recited in Appellant's dependent claim 10.

Page 4 of the Final Office Action states, "L-seal (25) provides sufficient space between the inner sheath and the anterograde sheath to contain the stent and therefore overlaps the claimed radial spacer."

Euteneuer describes that member 25 is glued to the inner diameter of the sleeve as a seal in order to hold the seal more tightly as pressure increases thereby decreasing the possibility of fluid leakage. (Col. 6, ln. 39-45; Fig. 2B). However, from a review of Figures 1-2, it is clear that member 25 is irrelevant to providing sufficient space between the catheter and either of sliding sleeves 14 or 16 because stent 17 is secured to the catheter by bands 18, and even without the member 25, sliding sleeves 14 and 16 can cover the stent 17 with plenty of clearance (they do not even touch the stent 17).

As such, Euteneuer does not describe "a radial spacer for providing sufficient space between the inner sheath and the anterograde sheath to contain the endoluminal device." Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 102(b) rejection of dependent claim 10.

6. Euteneuer does not describe that "the radial spacer is attached proximally to the distal tip" as recited in Appellant's dependent claim 11.

Page 5 of the Final Office Action states that "the radial spacer of Euteneuer is indirectly attached to the distal tip." However, as stated above, Euteneuer does not teach that anything is attached to the distal tip of the guide wire 50, directly or indirectly.

As such, Euteneuer does not describe that "the radial spacer is attached proximally to the distal tip" of the shaft. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 102(b) rejection of dependent claim 11.

D. The Euteneuer reference does not teach, suggest, or render obvious each and every element of Appellant's claims 31-33, 47, and 51.

1. Dependent claims 31-33 and 51, which depend directly or indirectly from independent claim 1 are not argued separately from the arguments presented above for independent claim 1.

Appellant respectfully submits that, for the reasons set forth above, independent claim 1 is allowable in view of the Euteneuer reference. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejections of dependent claims 31-33 and 51, which depend directly or indirectly from independent claim 1.

2. Euteneuer does not teach, suggest, or render obvious "an anterograde portion comprising a distal tip and an anterograde sheath attached proximally to the distal tip and mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder" as recited in Appellant's independent claim 47.

In rejecting independent claim 47, page 6 of the Final Office Action only addresses a balloon expandable stent placed between the inner sheath and stent and does not address the above-quoted language. Accordingly, the Final Office Action does not present a prima facie case of obviousness regarding the above-quoted claim language. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejection of independent claim 47.

3. Euteneuer does not teach, suggest, or render obvious "a shaft attached to the distal tip and extending concentrically through a central lumen defined by the anterograde portion and retrograde portion" as recited in Appellant's independent claim 47.

In rejecting independent claim 47, page 6 of the Final Office Action only addresses a balloon expandable stent placed between the inner sheath and stent and does not address the above-quoted language. Accordingly, the Final Office Action does not present a prima facie case of obviousness regarding the above-quoted claim language. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejection of independent claim 47.

4. Euteneuer does not teach, suggest, or render obvious "an inner sheath mounted concentrically over the shaft" as recited in Appellant's independent claim 47.

In rejecting independent claim 47, page 6 of the Final Office Action only addresses a balloon expandable stent placed between the inner sheath and stent and does not address the above-quoted language. Accordingly, the Final Office Action does not present a prima facie case of obviousness regarding the above-quoted claim language. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejection of independent claim 47.

5. Euteneuer does not teach, suggest, or render obvious "a retrograde portion including a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath in the retrograde portion of the introducer and extending distally over a retrograde portion of the endoluminal device, wherein the retrograde sheath and the anterograde sheath are laterally spaced from one another at least when the retrograde sheath is proximally retracted" as recited in Appellant's independent claim 47.

In rejecting independent claim 47, page 6 of the Final Office Action only addresses a balloon expandable stent placed between the inner sheath and stent and does not address the above-quoted language. Accordingly, the Final Office Action does not present a prima facie case of obviousness regarding the above-quoted claim

language. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejection of independent claim 47.

6. Euteneuer does not teach, suggest, or render obvious "an endoluminal device mounted concentrically over the inner sheath in the central lumen and having a distal portion contained by the anterograde portion and a proximal end contained by the retrograde portion, the distal portion constrained in the compressed configuration by the anterograde sheath and adapted to expand into an expanded state as the anterograde sheath is advanced distally" as recited in Appellant's independent claim 47.

In rejecting independent claim 47, page 6 of the Final Office Action only addresses a balloon expandable stent placed between the inner sheath and stent and does not address the above-quoted language. Accordingly, the Final Office Action does not present a prima facie case of obviousness regarding the above-quoted claim language. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejection of independent claim 47.

7. Euteneuer does not teach, suggest, or render obvious "an inflatable balloon mounted radially inside only the retrograde portion and sized to: engage and anchor the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration to minimize relative axial movement between the engaged, anchored, expanded proximal end of the device and the body lumen during unsheathing of the endoluminal device distal portion; and engage and anchor only a proximal portion of the endoluminal device after unsheathing of the distal portion of the endoluminal device" as recited in Appellant's independent claim 47.

In rejecting independent claim 47, page 6 of the Final Office Action only addresses a balloon expandable stent placed between the inner sheath and stent and does not address the entirety of the above-quoted language. Accordingly, the Final Office Action does not present a prima facie case of obviousness regarding the above-quoted claim language. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejection of independent claim 47.

E. The Euteneuer and Zadno-Azizi references, alone or in combination, do not teach, suggest, or render obvious each and every element of Appellant's claim 17.

Dependent claim 17, which depends from independent claim 1, is not argued separately for purposes of appeal from the arguments presented above for independent claim 1. That is, Appellant respectfully submits that the Euteneuer reference does not describe each and every element of independent claim 1. The Zadno-Azizi reference does not cure the deficiencies of the Euteneuer reference. That is, Euteneuer and Zadno-Azizi, alone or in combination, do not teach, suggest, or render obvious each and every element of Appellant's independent claim 1. Accordingly, Appellant respectfully requests reconsideration and withdrawal of the § 103(a) rejection of dependent claim 17, which depends from independent claim 1.

CONCLUSION

Appellants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner and/or members of the Board are invited to telephone Appellants' attorney Jason P. Lorfing at (612) 236-0132 to facilitate this appeal.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: **MS Appeal Brief-Patents** Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450, on this 23 day of April, 2010.

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2010-04-23
Date:

VIII. CLAIMS APPENDIX

1. (Previously Presented) An introducer, having a retrograde portion and an anterograde portion, for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration, the introducer comprising:

a shaft having a distal tip;

an inner sheath mounted concentrically over the shaft, wherein the endoluminal device is mounted concentrically over the inner sheath in the compressed configuration;

an anterograde sheath attached proximally to the distal tip, mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder;

anchoring means in at least one of the retrograde portion or the anterograde portion configured to:

engage and anchor only a proximal portion of the endoluminal device after unsheathing of a distal portion of the endoluminal device; and

minimize relative axial movement between the engaged and anchored proximal portion of the device and the body lumen during unsheathing of the distal portion of the endoluminal device; and

a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath in the retrograde portion of the introducer and extending distally over a retrograde portion of the endoluminal device, wherein the retrograde sheath and the anterograde sheath are laterally spaced from one another at least when the retrograde sheath is proximally retracted.

2. (Canceled)

3. (Previously Presented) The introducer of claim 1, wherein the anchoring means comprises an inflatable balloon at or near a proximal end of the device.

4. (Original) The introducer of claim 3, wherein the inner sheath defines a lumen connected to an inner region of the inflatable balloon for communication of a fluid to the balloon for inflation of the balloon.

5. (Original) The introducer of claim 3, wherein the inflatable balloon is mounted concentrically underneath a retrograde portion of the endoluminal device.

6. (Previously Presented) The introducer of claim 5, wherein the a proximally retractable retrograde sheath extends distally over the balloon.

7. (Original) The introducer of claim 6 further comprising a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer.

8. (Original) The introducer of claim 7, wherein the medial sheath has a distal end that terminates proximal of the balloon.

9. (Withdrawn) The introducer of claim 5, wherein the anterograde sheath extends proximally over the balloon and a retrograde portion of the endoluminal device.

10. (Original) The introducer of claim 1 further comprising a radial spacer for providing sufficient space between the inner sheath and the anterograde sheath to contain the endoluminal device.

11. (Original) The introducer of claim 10, wherein the radial spacer is attached proximally to the distal tip.

12. (Withdrawn) The introducer of claim 2, wherein the anchoring means comprises a holder in the anterograde portion.

13. (Withdrawn) The introducer of claim 12, wherein the holder is concentrically mounted to the inner sheath and adapted to prevent distal movement of the endoluminal device during distal advancement of the anterograde shaft.

14. (Withdrawn) The introducer of claim 13, wherein the endoluminal device has a length and the holder has a length that is less than the endoluminal device length.

15. (Withdrawn) The introducer of claim 12, wherein the anterograde sheath extends over an entire length of the endoluminal device.

16. (Withdrawn) The introducer of claim 1, wherein the anterograde sheath extends over an entire length of the endoluminal device.

17. (Previously Presented) The introducer of claim 1 further comprising:

a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of a proximal end of the endoluminal device.

18. (Withdrawn) The introducer of claim 17, wherein the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in the medial sheath for confining the extended portion between the retrograde sheath and the medial sheath with the retrograde sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the medial sheath.

19. (Withdrawn) The introducer of claim 2 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and wherein the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the inner sheath and the retrograde

sheath for confining the extended portion between the retrograde sheath and the inner sheath with the retrograde sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the inner sheath.

20. (Withdrawn) The introducer of claim 2 further comprising:

a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath; and

a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of a proximal end of the endoluminal device;

wherein the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the medial sheath and the retrograde sheath for confining the extended portion between the retrograde sheath and the medial sheath with the retrograde sheath in a first position and for releasing the extended portion with the retrograde sheath in a second, retracted position relative to the medial sheath.

21. (Withdrawn) The introducer of claim 2, wherein the anchoring means comprises a tether attached to a proximal end of the endoluminal device.

22. (Withdrawn) The introducer of claim 21 further comprising a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and wherein the tether is attached to a portion of the inner sheath.

23. (Withdrawn) The introducer of claim 22, wherein the tether extends proximally from the device a sufficient distance to terminate outside a body lumen through which the introducer is adapted to be introduced.

24. (Withdrawn) The introducer of claim 22, wherein a proximal end of the tether is attached to means for applying an electrical current or a torsional or tensional force.

25. (Withdrawn) The introducer of claim 21 further comprising:

a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and extending axially over a proximal end of the endoluminal device; and

a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of the endoluminal device proximal end.

26. (Withdrawn) The introducer of claim 25, wherein the tether is attached to one of the medial sheath, the retrograde sheath, or the inner sheath.

27. (Withdrawn) The introducer of claim 26, wherein the tether extends proximally from the device a sufficient distance to terminate outside a body lumen through which the introducer is adapted to be introduced.

28. (Withdrawn) The introducer of claim 27, wherein the medial sheath comprises a lateral channel through which the tether extends.

29. (Withdrawn) The introducer of claim 21, wherein the anterograde sheath extends over an entire length of the endoluminal device.

30. (Canceled)

31. (Previously Presented) The introducer of claim 1, wherein the anterograde portion extends over a greater length of the endoluminal device than the retrograde portion.

32. (Previously Presented) The introducer of claim 1, wherein the retrograde sheath and the anterograde sheath are laterally spaced from one another before the retrograde sheath is proximally retracted.

33. (Previously Presented) The introducer of claim 1, wherein the retrograde sheath and the anterograde sheath laterally overlap one another before the retrograde sheath is proximally retracted.

34.-46. (Canceled)

47. (Previously Presented) An introducer for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration, the introducer comprising:

an anterograde portion comprising a distal tip and an anterograde sheath attached proximally to the distal tip and mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer, the anterograde

sheath having an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder;

a shaft attached to the distal tip and extending concentrically through a central lumen defined by the anterograde portion and retrograde portion;

an inner sheath mounted concentrically over the shaft;

a retrograde portion including a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath in the retrograde portion of the introducer and extending distally over a retrograde portion of the endoluminal device, wherein the retrograde sheath and the anterograde sheath are laterally spaced from one another at least when the retrograde sheath is proximally retracted;

an endoluminal device mounted concentrically over the inner sheath in the central lumen and having a distal portion contained by the anterograde portion and a proximal end contained by the retrograde portion, the distal portion constrained in the compressed configuration by the anterograde sheath and adapted to expand into an expanded state as the anterograde sheath is advanced distally; and

an inflatable balloon mounted radially inside only the retrograde portion and sized to:

engage and anchor the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration to minimize relative axial movement between the engaged, anchored, expanded

proximal end of the device and the body lumen during unsheathing of the endoluminal device distal portion; and

engage and anchor only a proximal portion of the endoluminal device after unsheathing of the distal portion of the endoluminal device.

48. (Withdrawn) The introducer of claim 47 further comprising an inner sheath mounted concentrically over the shaft underneath the endoluminal device, the inner sheath defining a lumen connected to an inner region of the inflatable balloon for communication of a fluid to the balloon for inflation of the balloon, wherein the retrograde portion comprises a proximally retractable retrograde sheath mounted concentrically over the shaft and the inner sheath and extending distally over the balloon and a retrograde portion of the endoluminal device.

49. (Canceled)

50. (Withdrawn) The introducer of claim 5, wherein the anchoring means further comprises a holder in the anterograde portion concentrically mounted to the inner sheath and adapted to prevent distal movement of the endoluminal device during distal advancement of the anterograde shaft.

51. (Previously Presented) The introducer of claim 1, wherein the retrograde sheath and the anterograde sheath abut one another before the retrograde sheath is proximally retracted.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

As there are no appeals or interferences known to Appellant's Representatives which will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal, there are no copies of decisions rendered by a court or the Board to submit.